

REMARKS

Applicants have received and reviewed the Office Action dated April 17, 2009. A three month extension of time is filed herewith extending the time for response to October 17, 2009. Claims 1, 6-7 and 9-33 are pending and claims 12-20, 22-25 and 31-32 are withdrawn. Claims 1, 6-7, 9-11, 21, 26-30 and 33 are the subject of this Examination. Applicants have amended claims 1, 7 and 9 and introduced new claim 33. The Examiner may find support for the amendments throughout the specification, for example, at page 2, lines 27-30; Example 1; and the originally filed claims.

Applicants thank the Examiner for the careful review of this application and for withdrawing the previous rejections.

35 U.S.C. § 103(a)

At paragraph 11 of the Office Action, claims 1, 7, 9-11, 21, 26, 29 and 30 were rejected under 35 U.S.C. § 103(a) over Halskov (WO 81/02671) in view of Valducci (US 2002/0034541). Applicants respectfully traverse these rejections.

First, Applicants do not agree with the Office Action's characterization of the cited art or the presently claimed invention; however, without acquiescing to the rejections and solely to further prosecution, Applicants have amended claim 1.

In part, claim 1 one now recites a coated granulate "wherein the coated granulate comprises: a pharmaceutically acceptable binder" and "92 to 98% by weight of mesalazine or a pharmaceutically acceptable salt thereof." By contrast, the Office Action admits that Halskov only discloses a coated granulate with 78% mesalazine. Therefore, amended claim 1 recites a coated granulate with a significantly higher percent mesalazine when compared to Halskov.

At page 5 of the Office Action, the Examiner performs two weight percentage calculations based on the numbers presented on page 11 of Halskov. The first weight percent calculation is for mesalazine granulate prior to coating with ethyl cellulose and results in a 91% mesalazine per granulate. The second weight percent calculation is for mesalazine granulate after coating with ethyl cellulose and results in 78% mesalazine per granulate. Amended claim 1

recites a coated granulate (granulate after coating) comprising from 92 to 98% mesalazine by weight. A jump from 78% to 92% is a significant improvement.

Second, Applicants respectfully disagree with the position the Office Action takes on the first paragraph of page 7. Specifically, Applicants submit one novel aspect of the presently claimed invention is the ability to achieve specific release profiles while still maintaining a high drug load capacity.

Third, Applicants submit amended claim 1 is nonobvious over the combination of Halskov and Valducci because neither reference independently or in combination discloses, suggests, or makes obvious an oral pharmaceutical formulation in the form of a coated granulate in a sachet, wherein the coated granulate comprises a pharmaceutically acceptable binder and from 92 to 98% by weight of mesalazine or a pharmaceutically acceptable salt thereof.

Finally, Applicants submit that claims 7, 9-11, 21, 26 and 29-30 are in condition for allowance because they depend from amended claim 1.

Applicants respectfully request withdrawal of the above rejections and a notice of allowance for claims 1, 9-11, 21, 26 and 29-30.

At paragraph 12 of the Office Action, claims 6 and 27-28 were rejected under 35 U.S.C. 103(a) over Halskov in view of Valducci and further in view of Augsburg et al. (US 2002/0177579). Applicants respectfully traverse this rejection.

Applicants note claims 6 and 27-28 depend from amended claim 1. In view of the above arguments and amendments relating to claim 1, Applicants respectfully submit that claims 6 and 27-28 are in condition for allowance and request withdrawal of the above rejections and a notice of allowance.

In this response, Applicants have added new claim 33. Claim 33 recites a granulate with from 92 to 98% by weight of mesalazine or a pharmaceutically acceptable salt thereof. As discussed above, the cited references fail to disclose an amount this high. Second, claim 33 recites from 2 to 8% by weight of polyvinylpyrrolidone. At page 7 of the Action, the Examiner notes the cited prior art only discloses 9% polyvinylpyrrolidone.

Applicants submit claim 33 is nonobvious over the cited prior art for at least the above two reasons. Applicants respectfully request a notice of allowance for claim 33.

Reply to Office Action of April 17, 2009

Summary

In view of the above amendments and remarks, Applicants respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

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